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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,254	06/25/2003	Chih-Ming Chen	300.1003CON	3690

23280 7590 10/17/2006

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/603,254	Applicant(s) CHEN ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *76-84,88 and 89*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Sharmila S. Gollamudi
AU 1616

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 76-84 and 88-89 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13, and 15 of U.S. Patent No. 5,837,379 in view of Cheng et al (Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A(HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (1993), 10:1683-1687) is withdrawn in view of the filing of a Terminal Disclaimer filed 9/26/06. All other rejections of record are maintained.

Applicant arguments are substantially similar to those presented on 3/31/06 and have been fully addressed in the Final Office Action of 6/6/06.

Briefly applicant argues that although US '379 (Chen et al) teaches lovastatin, lovastatin is in a laundry list and thus there is not motivation to specifically select lovastatin. The applicant's arguments that the species disclosed are not 1) structurally similar, 2) the species taught are not sufficeintly small, and 3) the prior art does not specifically guide one to lovastatin in particular, are arguments pertaining to a rejection made under anticipation. The examiner notes that lovastatin is taught among several other drugs. Thus, as pointed out in the Finall Office Action of 3/31/06, the claims are rejected under obviousness and not anticipation since the examiner recognizes that one would not immediately envisage the use of lovastatin. However, Chen suggests the use of lovastin in the controlled release device and the motivation to select lovastatin comes from US '379 itself. Further, the examiner also relies on Cheng et al to provide motivation to specifically utilize lovastatin for reducing cholesterol serum levels. The examiner points out that the selection of a drug is prima facie obvious since it depends on the disease to be treated.

Applicant argues that nifedipine and lovastatin are not structurally similar. The examiner has not purported there is a structural similarity between nifedipine and lovastatin. Thus, this argument is unclear. Applicant argues that the controlled release device disclosed in Chen would not function the same and depends on the drug selected. However, applicant's arguments are mere arguments without any evidence. The examiner notes that Chen's disclosure is to the controlled release device and not the specific drug. Chen clearly states that various drugs may be used with the same controlled release effect. Thus, a skilled artisan would expect similar results irrespective of the particular drug utilized. Moreover, a skilled artisan would certainly expect the device to function in the same manner with the utilization of a drug suggested by the reference itself.

Applicant argues that the instant functional limitations have not been considered. The examiner has clearly considered the functional limitations as set forth in the rejection. Further, the examiner has addressed applicant's arguments in detail in the Final Office action and refers applicant to the examiner's position on page 7-8 of the Final Office Action of 3/31/06.

Thus, the rejection of claims 76-84 and 88-89 under 35 U.S.C. 103(a) as being unpatentable over US patent 5, 837,379 to Chen et al by itself or in view of Cheng et al (Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A(HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (1993), 10:1683-1687) is maintained.

Applicant argues the merits of the obviousness double patenting rejection over US 5,837,379. However, applicant's position is unclear since a Terminal Disclaimer has been filed over US '379.

Applicant states a Terminal Disclaimer over US 5,916,595 has been filed. However, the record indicates a Terminal Disclaimer has not been filed over US '595. Thus, the rejection of claims 76-84 and 88-89 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595 is maintained.

Applicant argues the merits of the obviousness double patenting rejection over US 6,485,748. The arguments are similar to those made prior to the Final Office action. The examiner refers applicant to page 14-15 of the Final Office Action of 3/31/06 in which the examiner fully addresses the arguments. Thus, the rejection of claims 76-84 and 88-89 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-14 of US patent 6,485,748 in view of Cheng et al (Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A(HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (1993), 10:1683-1687) is maintained.